

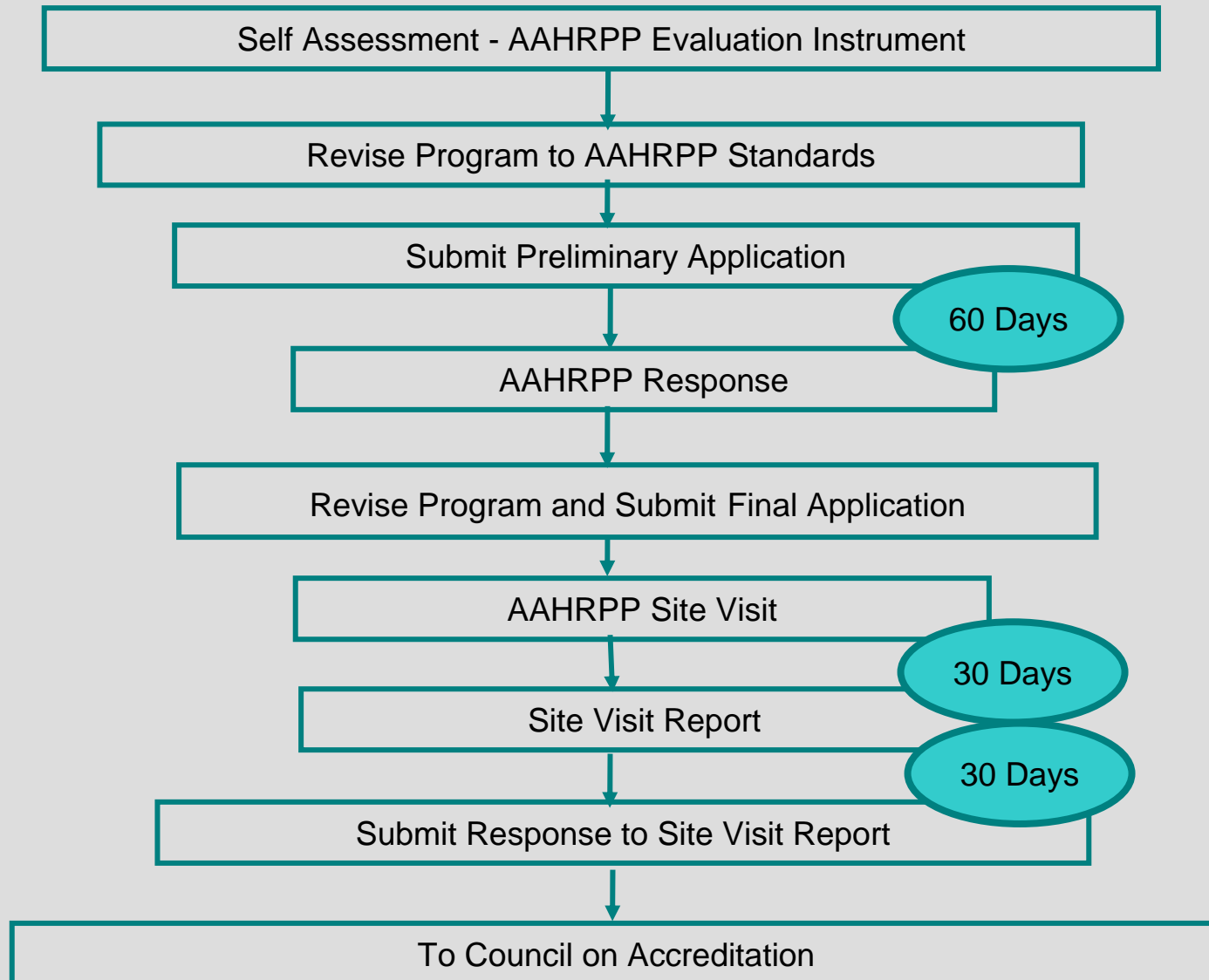
The Ins and Outs, Ups and Downs of Accreditation

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The Road to Accreditation



Getting Started

- Get management buy-in
- Establish Accreditation Team
- Create AAHRPP Manual
- Read everything
- Go to conferences
- Establish a time line (and stick to it)

Application Outline

Section A - Application Form

Section B - Program Overview

Section C - Element by Element Index

Section D - Supporting Documents

Final Application:

Section E - IRB Minutes

Section F - IRB Roster

Section G - Active Protocols

5 Domains 20 Standards 77 Elements

- Organization (5S - 26E)
- Research Review Unit (8S - 3E)
- Investigators (2S - 11E)
- Sponsored Research (3S - 5E)
- Participant (Community) Outreach (2S-4E)

Tips

- Site regulations and quote verbatim – Do Not paraphrase
- Review all directions/forms for consistency
- Do not create unnecessary policies and procedures
- Use simple, consistent formats
- Write once, refer many (WORM)
 - Reporting
 - Use same procedures. Example: Expedited Review
 - Initial Review
 - Modifications/Changes
 - Continuing Review
- Plan for implementation of promised changes
- Communicate with AAHRPP and use their Tip Sheets
- Use OHRP Charts

Hot Spots

- Conflict of Interest
 - Institutional
 - IRB Members/Consultants
 - Researchers/Immediate family members
- FDA
- Vulnerable Subjects
- Notifications and Reporting
- Appropriate IRB Expertise
- Community Outreach
- Continued Program Assessment

AAHRPP Focus - Outcome

- Strong Organizational awareness and support
- Clear lines of communication, authority and responsibility
- Policies and procedures:
 - Meet regulatory requirements
 - Appropriate for program needs
 - Clearly documented, communicated, implemented and enforced
 - Adhered to in actual practice as demonstrated during site visit

Challenges

- Painfully long and frustrating process
 - Demand on staff time and resources
 - Maintaining routine work duties
- Typically 2-3 years
 - Initial state of program
 - Number of staff assigned
 - Other responsibilities/demands
 - Council's determination (Qualified?)
- Must be maintained

Is it Worth It?

Excellent Way to Improve Program

- ▶ Forces in-depth program assessment
 - New and improved
 - policies and procedures
 - documentation of policies and procedures
 - Standardization and consistency
 - Better understanding and implementation of the regulations
 - Prompted IRB training
 - Encourages continual improvement
 - Plan to streamlined program
- ▶ Enhanced communication and awareness of HRPP
- ▶ Client recognition/expectation?
- ▶ IRB and Research staff excited to participate/anxious for outcome